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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,320	02/07/2002	Russell Mumper	434-400 DIV	5127

1009 7590 01/14/2011
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EXAMINER

ROGERS, JAMES WILLIAM

ART UNIT	PAPER NUMBER
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1618

MAIL DATE	DELIVERY MODE
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01/14/2011

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/072,320	Applicant(s) MUMPER ET AL.	
	Examiner JAMES W. ROGERS	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 November 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33,34,42-57 and 63-68 is/are pending in the application.
- 4a) Of the above claim(s) 47-50 and 52-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33,34,42-46,51,56,57 and 63-68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/28/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendments to the claims filed 11/03/2010 have been entered. Any objection\rejections from the previous office action filed 08/16/2010 not addressed below has been withdrawn.

As a preliminary matter applicants inquire on page 9 section 4 if the examiner withdrew the previous rejection of claim 63 for the limitation "from about 2:1 to about 4:1", the examiner did not make this rejection in the last office action, a non-final rejection after RCE, there is no longer a rejection for the above limitation.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 33-34,42-46,56-57,65 and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369), for the reasons set forth in the previous office actions filed 10/09/2009, 07/15/2010 and 08/16/2010.

Regarding applicant's new limitation that the anionic pH sensitive film forming copolymer is methacrylic acid and acrylic or methacrylic acid, Slavtcheff teaches a polymer which may be anionic comprised of monomer units where methacrylic acid and acrylic acid may be selected. See col 4 lines 44-54.

Response to Arguments

Applicant's arguments filed 11/03/2010 have been fully considered but they are not persuasive.

Applicants assert that Slavtcheff fails to teach or hint at using a pH sensitive anionic mucoadhesive layer for use on wet mucosal surfaces as claimed and only teaches its use for the skin.

The limitation on adhering the adhesive to a mucosal surface is just an intended use of the adhesive, the adhesive taught by the combination of Slavtcheff and Suzuki would be capable of the same use since the combination of references is within the scope of the adhesive claimed. Furthermore applicants claim skin as a mucosal site in claim 56, thus skin would not seem to be precluded by the claims as a mucosal site. The pH sensitive mucoadhesive layer is defined within the claim by what it comprises, a water-insoluble swellable anionic mucoadhesive polymer and at least one anionic pH-sensitive film-forming polymer. As disclosed in the previous office action Slavtcheff discloses an adhesive composition containing anionic film forming polymers and Carbomer structuring agent. Carbomer is described in applicant's specification and was previously claimed as a water-insoluble swellable anionic mucoadhesive polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol, thus Slavtcheff discloses the use of both of applicants claimed ingredients in the adhesive composition.

Applicant's state that Slavtcheff does not teach each and every element of the present claim set because the reference does not provide a reasonable expectation of success in using the ingredients described within that reference.

The relevance of this assertion is unclear; applicants are essentially stating that because Slavtcheff teaches the use of more than their own claimed ingredients there would be no expectation of success in using the ingredients within Slavtcheff including

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the same ingredients which are claimed. Slavtcheff teaches the same mucoadhesive layer claimed, therefore it is not deficient with respect to expectation of success since it teaches the exact same ingredients in combination. As noted previously the only piece missing from Slavtcheff is the claimed wax layer. As noted in previous office actions there would be a high expectation of success in adding the wax backing layer of Suzuki to the adhesive film of Slavtcheff.

Applicants further argue that Slavtcheff does not use the phrase “pH sensitive mucoadhesive polymer” when describing Carbomer in the adhesive layer.

This argument cannot be correct, simply because applicants call Carbomer or polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol by another name than Slavtcheff (describes it as a “structuring polymer”) does not mean that the compound is not the same. The same compound is the same no matter what the name is given to that compound.

Applicants assert that since the examiner said in a 112 2nd rejection in the previous office action that a trademark name cannot be used to identify any particular product, he presumably cannot use a commercial name for a teaching of a specific product in a prior art rejection.

While applicant's reasoning is interesting the examiner does not find it persuasive. The rejection was in regards to the claim set not to a description of a particular material by its commercial product name in the prior art, in this case a copolymer. In the description of Slavtcheff it clearly states the use of structuring agent Carbomer. In applicant's specification this commercial product is identified as a water

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insoluble swellable anionic mucoadhesive polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol, thus the examiner must presume that Slavtcheff is describing the same polymer claimed. See [0022] of USPGPUB US 2002/0132008 A1. Furthermore as evidence the examiner relies upon the teaching of Guo ("Carbopol® Polymers for Pharmaceutical Drug Delivery Applications", Drug Delivery Technology, Vol. 3 No. 6 September 2003), which clearly states that Carbopol polymers are polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol.

Claims 33,34,42-46,51,56,57 and 63-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Slavtcheff et al (US 6,270,783 B1) in view of Suzuki et al. (US 4,715,369) in view of Mantelle et al. (US 6,562,363 B1), for the reasons set forth in the previous office actions filed 10/09/2009, 07/15/2010 and 08/16/2010.

Claims 33-34,42-46,56-57 and 63-67 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle et al. (US 6,562,363 B1) in view of Suzuki et al. (US 4,715,369), for the reasons set forth in the previous office action filed 08/16/2010.

Response to Arguments

Applicant's arguments filed 11/03/2010 have been fully considered but they are not persuasive.

Applicants assert there is no reason for the skilled artisan to consider the combination of ingredients claimed from the combination of Slavtcheff and Mantelle or Mantelle alone with a reasonable expectation of success independent of mere

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recitations of ingredients to arrive at applicants claimed pH-sensitive mucoadhesive layer as claimed.

As applied above applicant's argument that the references do not describe a pH-sensitive anionic mucoadhesive for delivering a molecule of interest to mucosal area is not persuasive, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. Clearly adhesive technology is a mature field and one of ordinary skill in the art would have a high expectation of success in adding or using adhesive ingredients which are known in the prior art. There is nothing difficult or undue in using compounds that are described as useful in the same field of endeavor, in this instance adhesives, and substituting or combining those compounds.

Applicants argue that Mantelle expressly leads on of ordinary skill in the art to use PVP.

As noted previously one of ordinary skill in the art could combine any one of the disclosed adhesive compounds of Mantelle and add them in the adhesive of Slavtcheff. In addition to the rebuttal above even if one of ordinary skill in the art added the PVP taught in Mantelle to an adhesive composition it would not be precluded from independent claims 33, 66 and 67. Applicants claim an adhesive, Mantelle teaches an adhesive containing PVP, clearly PVP would not materially affect the basic and novel characteristic(s) of the claimed invention drawn to an adhesive since Mantelle uses this ingredient and the composition functions as an adhesive.

Applicants assert that Mantelle's description of Noveon and Eudragit polymers encompasses a wide range of polymers with different properties and therefore the requisite expectation of success in making applicants claimed adhesive is lacking. The relevance of this assertion is unclear, Mantelle teaches the use of the specific Eudragit polymers S100 and L100 which are described in applicants specification ([0072] of USPGPUB US 2002/0132008 A1) as the most preferred anionic Eudragit pH sensitive film forming copolymers. In applicant's specification the commercial product Noveon is identified as a water insoluble swellable anionic mucoadhesive polyacrylic acid cross-linked with polyalkenyl ether or divinyl glycol, thus the examiner must presume that Mantelle is describing the same polymer. See [0022] of USPGPUB US 2002/0132008 A1. The polymers of Mantelle are the same polymers used by applicants and are clearly taught within Mantelle as being useful ingredients in the described bioadhesive, thus the expectation of success in selecting such polymers for use in an adhesive composition would be very high. Mantelle teaches the same mucoadhesive layer claimed, therefore it is not deficient with respect to expectation of success since it teaches the exact same ingredients in combination. As noted previously the only piece missing from Mantelle is the claimed wax layer. As noted in previous office actions there would be a high expectation of success in adding the wax backing layer of Suzuki to the adhesive film of Mantelle.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you

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have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/J. W. R./

Examiner, Art Unit 1618

/Michael G. Hartley/

Supervisory Patent Examiner, Art Unit 1618